DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 26 2010

Re: Ablavar, previously Vasovist
Patent Nos. 6,676,929 and 7,060,250
Docket Nos.: FDA-2009-E-0165
FDA-2009-E-0169

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 6,676,929 and 7,060,250, filed by Epix Pharmaceuticals, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Ablavar, previously Vasovist[1] (gadofosveset trisodium), the human drug product claimed by the patents.

The total length of the regulatory review period for Ablavar (gadofosveset trisodium) is 4,508 days. Of this time, 2,673 days occurred during the testing phase and 1,835 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: August 21, 1996.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 21, 1996.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 15, 2003.

   FDA has verified the applicant's claim that the new drug application (NDA) 21-711 was submitted on December 15, 2003.

3. The date the application was approved: December 22, 2008.

   FDA has verified the applicant's claim that NDA 21-711 was approved on December 22, 2008.

[1] According to FDA records, the trade name of the product has been changed from Vasovist to Ablavar. For purposes of patent term restoration, we will refer to the product as Ablavar.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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